REMARKS

Claims 1-12 are pending in the application. Of these, claims 4-5 and 7-12 are withdrawn from consideration.

Claims 1-12 are amended herein to delete recitations relating to "prevention".

No new matter is presented.

Upon entry of the Amendment, claims 1-3 and 6 will be all of the claims pending in the application for examination.

I. Information Disclosure Statements

(1) The Examiner has returned the signed and initialed copy of the Forms PTO/SB/08 submitted with the IDSs filed on January 13, 2009 and February 26, 2009, thereby confirming that the references therein have been considered by the Examiner.

(2) Regarding the IDS filed March 12, 2007, the Examiner indicated that all the references cited on Form SB/08 were considered, except for the two NPL references. The Examiner stated that those two references were not considered because the English translations were not provided to the Office. The Examiner is not correct.

It was previously explained in the IDS filed March 12, 2007 that the English translation of the International Preliminary Report on patentability (Chapter I) with written opinion of the International Searching Authority received December 22, 2006, provides a concise explanation of the relevance of the two NPL references, namely, Gekkan Hodanren and Geriatr Med, which are in Japanese.

In this regard, together with the IDS filed March 12, 2007, a copy of the English translation of the International Preliminary Report on patentability (Chapter I) with written opinion of the International Searching Authority has been submitted.

Thus, Applicants are in compliance with the rules and respectfully request the Examiner to consider the two NPL references listed on the Form SB/08 filed March 12, 2007 and return an initialed copy with the next Action.

II. Response to Objection to the Specification

The Examiner objected to the Abstract as having two paragraphs. The Abstract is also objected to because of the presence of legal phraseology "comprising".

A new Abstract is submitted herewith, thereby obviating the objection to the specification.

Accordingly, Applicants respectfully request withdrawal of the objection.

III. Response to Claim Rejection under 35 U.S.C. § 112

Claims 1-3 and 6 are rejected under 35 U.S.C. §112, first paragraph, because, according to the Examiner, the specification, while being enabling for the treatment of overactive bladder accompanied with neurogenic disorders, allegedly does not reasonably provide enablement for prevention of overactive bladder accompanied with neurogenic disorders.

The claims are amended herein by deleting recitations relating to "prevention", thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

IV. Response to Claim Rejections under 35 U.S.C. § 103

Claims 1-3 and 6 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shimoyama et al. (European Patent Application No. EP 1358889 A1; "Shimoyama") in view of Garvey et al. (U.S. Patent Application Publication No. 2002/0143007A1; "Garvey").

Applicants respectfully traverse the rejection.

"Overactive bladder (OAB)" is a storage disorder often accompanied with neurogenic disorder, lower urinary tract obstruction and others, defined as a disease based on symptoms of urgency, usually with frequency and with or without urge incontinence (see paragraph [0004] of the present specification). Among them, the present invention relates to a method for the treatment of overactive bladder accompanied with neurogenic disorders. This is supported by the efficacy of Compound 1 (KMD-3213) on the micturition interval and frequency of involuntary contraction in the filling phase in a rat spinal cord injured OAB model (see Example 1 and Figures 1 and 2).

On the other hand, Shimoyama discloses an invention related to a method for the therapy of lower urinary tract symptoms including administration of an α1 receptor blocker (claim 4). As the Examiner understands, "lower urinary tract symptoms" do not include the symptom of urinary disturbance due to disturbance of nerve controlling the lower urinary tract (see paragraph [0015]). Shimoyama discloses that there have been attempts for the use of α receptor blockers for the urinary disturbance due to (2) abnormality of urination-controlling nerve (see paragraph [0003]). However, regarding the efficacy of the use of any specific α receptor blockers, Shimoyama only discloses that it has been confirmed that tamsulosin is clinically effectively for the therapy of neurogenic bladder in PCT/JP99/03343 (see paragraph [0007]). There is no disclosure about the efficacy of other α receptor blockers on the urinary disturbance due to (2) abnormality of urination-controlling nerve in Shimoyama.

PCT/JP99/03343 (WO 00/00187A1, the corresponding European patent application; EP1088551, a copy of which is attached for the Examiner's convenience) discloses: a pharmaceutical composition for the therapy of voiding dysfunction associated with neurogenic bladder containing tamsulosin (for example, claim 1 and paragraph [0052]); in the urinary dysfunction associated with neurogenic bladder, there are a voiding dysfunction and a st[o]rage dysfunction" and "in the voiding dysfunction, symptoms such as retardation of initiation of urination, prolongation of time for urination intermittent urination, minute urinary stream, etc. appear" (see paragraph [0007]); and the results of the clinical test to patients of voiding dysfunction associated with neurogenic bladder (see paragraphs [0038]-[0052], Test Example 1). Thus, there is no disclosure or suggestion regarding the storage dysfunction such as urinary urgency.

That is, although Shimoyama discloses that it has been confirmed that tamsulosin is clinically effectively for the therapy of neurogenic bladder, there is only disclosure of PCT/JP99/00343 as the basis, which at best discloses tamsulosin is useful for the voiding dysfunction of neurogenic bladder.

Regarding Garvey, there is no experimental data on overactive bladder. Garvey only provides experimental data relating to sexual dysfunction (Figures 1-11).

Therefore, a skilled artisan would not have been motivated to use the indoline derivative represented by the formula (I) of the present application for the treatment of OAB accompanied

with neurogenic disorders that is a storage dysfunction with a reasonable expectation of success based on the teachings of the cited references, whether taken alone or in combination.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: November 30, 2010